

June 26, 2019



U.S. Department
of Transportation

East Building, PHH-30
1200 New Jersey Avenue S.E.
Washington, D.C. 20590

**Pipeline and Hazardous
Materials Safety Administration**

DOT-SP 16308
(THIRD REVISION)

EXPIRATION DATE: 2021-01-31

(FOR RENEWAL, SEE 49 CFR 107.109)

1. GRANTEE: Vero Biotech LLC
Atlanta, GA
2. PURPOSE AND LIMITATION:
 - a. This special permit authorizes the transportation in commerce of permeation devices that are used in medical devices in lieu of use for calibrating air quality monitoring devices. This special permit provides no relief from the Hazardous Materials Regulations (HMR) other than as specifically stated herein. The most recent revision supersedes all previous revisions.
 - b. The safety analyses performed in the development of this special permit only considered the hazards and risks associated with the transportation in commerce.
 - c. No party status will be granted to this special permit.
3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR 173.175 in that these permeation devices are not used for calibrating air quality monitoring devices.
5. BASIS: This special permit is based on the application of Vero Biotech LLC dated January 30, 2018 submitted in accordance with § 107.105, the public proceeding thereon, and additional information submitted February 19, 2019.

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6. HAZARDOUS MATERIALS (49 CFR 172.101):

Hazardous Materials Description			
Proper Shipping Name	Hazard Class/ Division	Identification Number	Packing Group
Dinitrogen tetroxide*	2.3	UN1067	N/A

*See paragraph 7.b. below.

7. SAFETY CONTROL MEASURES:a. PACKAGING: The packaging is as follows:

(1) The inner packaging is a hermetically sealed glass ampule containing no more than 2 mL of hazardous material;

(2) The ampule is contained in a stainless steel or titanium permeation device;

(3) The permeation device and a soda lime-filled inerting chamber capable of absorbing all of the hazardous material are placed inside a sealed impact-resistant plastic cassette;

(4) The soda lime-filled inerting chamber is surrounded by plastic with a minimum thickness of 1.5 mm;

(5) The completed cassette is placed in a hermetically sealed aluminum foil pouch secondary packaging;

(6) The secondary package is then placed in a fiberboard outer packaging surrounded by foam inner packaging inserts for shipment; and

(7) The completed package must be capable of meeting the requirements of § 173.175(e) and (f).

b. OPERATIONAL CONTROLS: The permeation device identified in the test report and submitted with the application dated November 7, 2014 is not subject to the Hazardous Materials Regulations provided the permeation device meets the terms of this special permit and the requirements in § 173.175(a) through (g).

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c. MARKING: Each package covered under the terms of this special permit must be plainly and durably marked "DOT-SP 16308" in accordance with § 172.301(c). This marking must comply with § 172.304.

8. SPECIAL PROVISIONS:

a. Under the terms of this special permit, the grantee may only offer hazardous materials (i.e., the grantee is not authorized as a carrier).

b. A person who is not a holder of this special permit who receives a package covered by this special permit may reoffer it for transportation provided no modification or change is made to the package and it is reoffered for transportation in conformance with this special permit and the HMR.

c. A current copy of this special permit must be maintained at each facility where the package is offered or reoffered for transportation.

9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle, cargo aircraft, cargo vessel, passenger-carrying aircraft, and rail freight.

10. MODAL REQUIREMENTS: A current copy of this special permit must be carried aboard each cargo vessel, aircraft, or motor vehicle used to transport packages covered by this special permit. The shipper must furnish a copy of this special permit to the air carrier before or at the time the shipment is tendered.

11. COMPLIANCE: Failure by a person to comply with any of the following may result in suspension or revocation of this special permit and penalties prescribed by the Federal hazardous materials transportation law, 49 U.S.C. 5101 et seq:

- o All terms and conditions prescribed in this special permit and the Hazardous Materials Regulations, 49 CFR Parts 171-180.
- o Persons operating under the terms of this special permit must comply with the security plan requirement in Subpart I of Part 172 of the HMR, when applicable.

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- o Registration required by § 107.601 et seq., when applicable.

Each "Hazmat employee", as defined in § 171.8, who performs a function subject to this special permit must receive training on the requirements and conditions of this special permit in addition to the training required by §§ 172.700 through 172.704.

No person may use or apply this special permit, including display of its number, when this special permit has expired or is otherwise no longer in effect.

Under Title VII of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU) – "The Hazardous Materials Safety and Security Reauthorization Act of 2005" (Pub. L. 109-59), 119 Stat. 1144 (August 10, 2005), amended the Federal hazardous materials transportation law by changing the term "exemption" to "special permit" and authorizes a special permit to be granted up to two years for new special permits and up to four years for renewals.

12. REPORTING REQUIREMENTS: Shipments or operations conducted under this special permit are subject to the Hazardous Materials Incident Reporting requirements specified in 49 CFR §§ 171.15 Immediate notice of certain hazardous materials incidents, and 171.16 Detailed hazardous materials incident reports. In addition, the grantee(s) of this special permit must notify the Associate Administrator for Hazardous Materials Safety, in writing, of any incident involving a package, shipment or operation conducted under terms of this special permit.

Issued in Washington, D.C.:



for William Schoonover
Associate Administrator for Hazardous Materials Safety

June 26, 2019

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Material Safety Administration, U.S. Department of Transportation, East Building PHH-30, 1200 New Jersey Avenue, Southeast, Washington, D.C. 20590.

Copies of this special permit may be obtained by accessing the Hazardous Materials Safety Homepage at http://hazmat.dot.gov/sp_app/special_permits/spec_perm_index.htm. Photo reproductions and legible reductions of this special permit are permitted. Any alteration of this special permit is prohibited.

PO: BenMoore/TG